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10/526,072	02/28/2005	Kazuhisa Sugimura	SUGIMURA4	8316

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EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,072	SUGIMURA ET AL.	
	Examiner	Art Unit	
	ZACHARY SKELDING	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed January 17, 2008 is acknowledged.

   Claims 1-10, 12-20 and 23-33 have been canceled.

   Claims 11, 21 and 22 have been amended.

   Claims 11, 21 and 22 are pending.

   Claims 11, 21 and 22 are under examination as they read on a gene fragment encoding an anti-IL-6 antibody, including an anti-IL-6 scFv antibody, wherein the elected species of anti-IL-6 scFv antibody is an scFv that does not comprise a portion of the human antibody CH/CL chain.

2. The previous rejection under 35 U.S.C. § 112, 2nd paragraph has been withdrawn in view of applicant's amendment to the claims.

   The previous rejection under 35 U.S.C. § 102(b) has been withdrawn in view of applicant's amendment to the claims.

   New Grounds of Rejection necessitated by applicant's amendments to the claims are put forth below.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

   The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while *being enabling for* a gene fragment coding for a single chain Fv of a human anti-human IL-6 antibody that binds to human IL-6 with a dissociation constant (K_D) of 1.0×10^{-8} M or less, said gene fragment consisting of a gene fragment coding for a VH chain of said human anti-human IL-6 antibody bound to a gene fragment coding for a VL chain of said human anti-human IL-6 antibody; wherein complementarity determining regions (CDR1 to CDR3) of said VH chain have the following amino acid sequences: CDR1: Lys Tyr Tyr Met Ala (SEQ ID NO: 5), CDR2: Thr Ile Set Asn Set Gly Asp Ile Ile Asp Tyr Ala Asp Set Val Arg Gly (SEQ ID NO: 6), CDR3: Glu Tyr Phe Phe Ser Phe Asp Val (SEQ ID NO: 7), and/or complementarity determining regions (CDR1 to CDR3) of said VL chain have the following amino acid sequences: CDR1: Arg Ala Ser Gln Asp Ile Arg Asn Trp Val Ala (SEQ ID NO: 8), CDR2: Asp Gly Ser Ser Leu Gln Ser (SEQ ID NO: 9), CDR3: Gln Gln Ser Asp Ser Thr Pro Ile Thr Phe (SEQ ID NO: 10) and for a gene fragment coding for a single chain Fv of a human anti-human IL-6 antibody that binds to human IL-6 with a

dissociation constant (K_D) of 1.0 x 10^{-8} M or less, said gene fragment consisting of a gene fragment coding for a VH chain of said human anti-human IL-6 antibody bound to a gene fragment coding for a VL chain of said human anti-human IL-6 antibody, wherein said VH chain has the amino acid sequence depicted in SEQ ID NO: 2 and/or said VL chain has the amino acid sequence depicted in SEQ ID NO: 4 *does not reasonably provide enablement for* a gene fragment coding for a single chain Fv of a human anti-human IL-6 antibody that binds to human IL-6 and to thereby block binding between IL-6 and its receptor, said gene fragment consisting of a gene fragment coding for a VH chain of said human anti-human IL-6 antibody bound to a gene fragment coding for a VL chain of said human anti-human IL-6 antibody; wherein complementarity determining regions (CDR1 to CDR3) of said VH chain have the following amino acid sequences: CDR1: Lys Tyr Tyr Met Ala (SEQ ID NO: 5), CDR2: Thr Ile Set Asn Set Gly Asp Ile Ile Asp Tyr Ala Asp Set Val Arg Gly (SEQ ID NO: 6), CDR3: Glu Tyr Phe Phe Ser Phe Asp Val (SEQ ID NO: 7), and/or complementarity determining regions (CDR1 to CDR3) of said VL chain have the following amino acid sequences: CDR1: Arg Ala Ser Gln Asp Ile Arg Asn Trp Val Ala (SEQ ID NO: 8), CDR2: Asp Gly Ser Ser Leu Gln Ser (SEQ ID NO: 9), CDR3: Gln Gln Ser Asp Ser Thr Pro Ile Thr Phe (SEQ ID NO: 10) or for a gene fragment coding for a single chain Fv of a human anti-human IL-6 antibody that binds to human IL-6 and to thereby block binding between IL-6 and its receptor, said gene fragment consisting of a gene fragment coding for a VH chain of said human anti-human IL-6 antibody bound to a gene fragment coding for a VL chain of said human anti-human IL-6 antibody, wherein said VH chain has the amino acid sequence depicted in SEQ ID NO: 2 and/or said VL chain has the amino acid sequence depicted in SEQ ID NO: 4 or a gene fragment coding for a single chain Fv of a human anti-human IL-6 antibody that binds to human IL-6 and to thereby block binding between IL-6 and its receptor, said gene fragment consisting of a gene fragment coding for a VH chain of said human anti-human IL-6 antibody bound to a gene fragment coding for a VL chain of said human anti-human IL-6 antibody, wherein said VH chain has the amino acid sequence depicted in SEQ ID NO: 2 and/or said VL chain has the amino acid sequence depicted in SEQ ID NO: 4 wherein one or several amino acids are deleted, substituted or added in the amino acid sequences of said VH chain and/or said VL chain wherein said VH chain and VL chain bind to human IL-6 to thereby block binding between IL-6 and its receptor.

Claims 11, 21 and 22 as amended read on human anti-human IL-6 antibodies that "block binding between IL-6 and its receptor," which, when given its broadest reasonable interpretation consistent with the instant specification and the knowledge in the art, reads on blocking the binding between IL-6 and the IL-6Rα polypeptide, or blocking the binding between IL-6 and gp130 in the context of an IL-6/IL-6Rα complex, or blocking the binding of IL-6 to α2-macroglobulin (see, for example, Chow et al., Biochemistry. 2001 Jun 26;40(25):7593-603, in particular page 7594, figure 1A and left column, 1st paragraph and page 7602, left column, 1st paragraph; Matsuda et al., J Immunol. 1989 Jan 1;142(1):148-52, of record, in particular Discussion on page 151). Each of these interactions "between IL-6 and its receptor" are mediated by distinct regions of IL-6.

Thus, the skilled artisan would not reasonably expect or predict a given human anti-human IL-6 antibody, such as a single chain Fv consisting of a gene fragment coding for a VH chain and a VL chain with complementarity determining regions (CDR1 to CDR3) of said VH chain having the following amino acid sequences: CDR1: Lys Tyr Tyr Met Ala (SEQ ID NO: 5), CDR2: Thr Ile Set Asn Set Gly Asp Ile Ile Asp Tyr Ala Asp Set Val Arg Gly (SEQ ID NO: 6), CDR3: Glu Tyr Phe Phe Ser Phe Asp Val (SEQ ID NO: 7), and complementarity determining regions (CDR1 to CDR3) of said VL chain have the following amino acid sequences: CDR1: Arg Ala Ser Gln Asp Ile Arg Asn Trp Val Ala (SEQ ID NO: 8), CDR2: Asp Gly Ser Ser Leu Gln Ser (SEQ ID NO: 9), CDR3: Gln Gln Ser Asp Ser Thr Pro Ile Thr Phe (SEQ ID NO: 10) to be able to block binding between IL-6 and IL-6Rα polypeptide, AND gp130 in the context of an IL-6/IL-6Rα complex, AND α2-macroglobulin.

Moreover, given the diverse interactions between IL-6 and these various molecules, far more than routine experimentation would be required of the skilled artisan to isolate a single chain Fv consisting of a gene fragment coding for a VH chain and a VL chain with complementarity determining regions (CDR1 to CDR3) of said VH chain having the following amino acid sequences: CDR1: Lys Tyr Tyr Met Ala (SEQ ID NO: 5), CDR2: Thr Ile Set Asn Set Gly Asp Ile Ile Asp Tyr Ala Asp Set Val Arg Gly (SEQ ID NO: 6), CDR3: Glu Tyr Phe Phe Ser Phe Asp Val (SEQ ID NO: 7) or complementarity determining regions (CDR1 to CDR3) of said VL chain have the following amino acid sequences: CDR1: Arg Ala Ser Gln Asp Ile Arg Asn Trp Val Ala (SEQ ID NO: 8), CDR2: Asp Gly Ser Ser Leu Gln Ser (SEQ ID NO: 9), CDR3: Gln Gln Ser Asp Ser Thr Pro Ile Thr Phe (SEQ ID NO: 10) capable of blocking binding between IL-6 and its receptor.

Furthermore, with respect to the limitation recited in claim 22 (emphasis added) "*...wherein one or several amino acids are deleted, substituted or added in the amino acid sequences of said VH chain and/or said VL chain*, wherein said Vh chain and Vl chain bind to human IL-6 to thereby block binding between Il-6 and its receptor", essentially as stated in the prior Office Action mailed October 17, 2007, this limitation given its broadest reasonable interpretation consistent with the instant specification and the knowledge in the art, comprises amino acid deletions and/or substitutions and/or additions in the Vh and/or Vl chains, without an upper limit on the number of changes given that the claims recite "one or several" and the meaning of "several" is not defined in the instant specification.

Applicant argues that the claim reciting this limitation is enabled because the claim recites the functional limitation "wherein said Vh chain and Vl chain bind to human IL-6 to thereby block binding between Il-6 and its receptor" in conjunction with the structural limitation "wherein one or several amino acids are deleted, substituted or added in the amino acid sequences of said VH chain and/or said VL chain."

Applicant's arguments have been considered, but have not been found convincing, essentially for the reasons of record as put forth in the Office Action mailed October 17, 2007.

As essentially stated in the Office Action mailed October 17, 2007, the instant specification discloses the production and screening of a phage scFv library based on human Vh and Vl cDNAs against human IL-6, the isolation of the IL6gk3-2 clone, which was sequenced to yield SEQ ID NOs: 2 (Vh), 4 (Vl), 5-7 (Vh CDRs 1-3) and 8-10 (Vl CDRs 1-3) and shown to have the ability to inhibit the IL-6 dependent proliferation response of IL-6 dependent cell line KT-3 (see pages 6-9 and Figure 3). The instant specification also discloses other IL6gk3- and 4- clones which do not appear to have been characterized other than measuring their ability to bind IL-6 (see Figure 1).

However, the specification does not give sufficient direction or guidance for the skilled artisan to go about making a gene fragment coding for a single chain Fv of a human anti-human IL-6 antibody that binds to human IL-6 and to thereby block binding between IL-6 and its receptor, said gene fragment consisting of a gene fragment coding for a VH chain of said human anti-human IL-6 antibody bound to a gene fragment coding for a VL chain of said human anti-human IL-6 antibody, wherein said VH chain has the amino acid sequence depicted in SEQ ID NO: 2 and/or said VL chain has the amino acid sequence depicted in SEQ ID NO: 4 wherein one or several amino acids are deleted, substituted or added in the amino acid sequences of said VH chain and/or said VL chain wherein said VH chain and VL chain bind to human IL-6 to thereby block binding between IL-6 and its receptor, without an upper limit on the number of changes.

For example, the instant specification does not give direction or guidance to the skilled artisan as to which amino acids can be deleted and/or substituted and/or added to the Vh and/or Vl chains of a single chain Fv anti-IL-6 antibody consisting of a gene fragment coding for the Vh chain of SEQ ID NO: 2 and/or the Vl chain of SEQ ID NO: 4, without an upper limit on the number of changes given the unpredictability in the art of making mutations in antibody Vh and Vl regions, particular the CDRs, essentially for the reasons of record stated in the Office Action mailed October 17, 2007 in view of the teachings of Janeway, Vajdos, Rudikoff, Colman and Chien, of record. Rather, the instant claims encompass an invention of tremendous scope, and essentially calls for trial and error by the skilled artisan using techniques known in the art to begin discovering the claimed invention without assisting the skilled artisan in such an endeavor, which is insufficient to constitute adequate enablement.

The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Thus, undue experimentation would be required to produce the claimed invention commensurate with the scope of the claims from the written disclosure alone. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

5. Claims 11, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of a gene fragment coding for a single chain Fv of a human anti-human IL-6 antibody that binds to human IL-6 with a dissociation constant (K_D) of 1.0×10^{-8} M or less, said gene fragment consisting of a gene fragment coding for a VH chain of said human anti-human IL-6 antibody bound to a gene fragment coding for a VL chain of said human anti-human IL-6 antibody; wherein complementarity determining regions (CDR1 to CDR3) of said VH chain have the following amino acid sequences: CDR1: Lys Tyr Tyr Met Ala (SEQ ID NO: 5), CDR2: Thr Ile Set Asn Set Gly Asp Ile Ile Asp Tyr Ala Asp Set Val Arg Gly (SEQ ID NO: 6), CDR3: Glu Tyr Phe Phe Ser Phe Asp Val (SEQ ID NO: 7), and/or complementarity determining regions (CDR1 to CDR3) of said VL chain have the following amino acid sequences: CDR1: Arg Ala Ser Gln Asp Ile Arg Asn Trp Val Ala (SEQ ID NO: 8), CDR2: Asp Gly Ser Ser Leu Gln Ser (SEQ ID NO: 9), CDR3: Gln Gln Ser Asp Ser Thr Pro Ile Thr Phe (SEQ ID NO: 10) and for a gene fragment coding for a single chain Fv of a human anti-human IL-6 antibody that binds to human IL-6 with a dissociation constant (K_D) of 1.0×10^{-8} M or less, said gene fragment consisting of a gene fragment coding for a VH chain of said human anti-human IL-6 antibody bound to a gene fragment coding for a VL chain of said human anti-human IL-6 antibody, wherein said VH chain has the amino acid sequence depicted in SEQ ID NO: 2 and/or said VL chain has the amino acid sequence depicted in SEQ ID NO: 4.

However, applicant is not in possession of a gene fragment coding for a single chain Fv of a human anti-human IL-6 antibody that binds to human IL-6 and to thereby block binding between IL-6 and its receptor, said gene fragment consisting of a gene fragment coding for a VH chain of said human anti-human IL-6 antibody bound to a gene fragment coding for a VL chain of said human anti-human IL-6 antibody; wherein complementarity determining regions (CDR1 to CDR3) of said VH chain have the following amino acid sequences: CDR1: Lys Tyr Tyr Met Ala (SEQ ID NO: 5), CDR2: Thr Ile Set Asn Set Gly Asp Ile Ile Asp Tyr Ala Asp Set Val Arg Gly (SEQ ID NO: 6), CDR3: Glu Tyr Phe Phe Ser Phe Asp Val (SEQ ID NO: 7), and/or complementarity determining regions (CDR1 to CDR3) of said VL chain have the following amino acid sequences: CDR1: Arg Ala Ser Gln Asp Ile Arg Asn Trp Val Ala (SEQ ID NO: 8), CDR2: Asp Gly Ser Ser Leu Gln Ser (SEQ ID NO: 9), CDR3: Gln Gln Ser Asp Ser Thr Pro Ile Thr Phe (SEQ ID NO: 10) or for a gene fragment coding for a single chain Fv of a human anti-human IL-6 antibody that binds to human IL-6 and to thereby block binding between IL-6 and its receptor, said gene fragment consisting of a gene fragment coding for a VH chain of said human anti-human IL-6 antibody bound to a gene fragment coding for a VL chain of said human anti-human IL-6 antibody, wherein said VH chain has the amino acid sequence depicted in SEQ ID NO: 2 and/or said VL chain has the amino acid sequence depicted in SEQ ID NO: 4 or a gene fragment coding for a single chain Fv of a human anti-human IL-6 antibody that binds to human IL-6 and to thereby block binding

between IL-6 and its receptor, said gene fragment consisting of a gene fragment coding for a VH chain of said human anti-human IL-6 antibody bound to a gene fragment coding for a VL chain of said human anti-human IL-6 antibody, wherein said VH chain has the amino acid sequence depicted in SEQ ID NO: 2 and/or said VL chain has the amino acid sequence depicted in SEQ ID NO: 4 wherein one or several amino acids are deleted, substituted or added in the amino acid sequences of said VH chain and/or said VL chain wherein said VH chain and VL chain bind to human IL-6 to thereby block binding between IL-6 and its receptor.

The instant specification does not provide adequate written description of the broad genus of gene fragments encompassed by instant claims because relevant identifying characteristics for the gene fragments encompassed by the instant claims, such as the particular *structural or other physical and/or chemical characteristics that are critical to the function* of the claimed gene fragments, i.e., producing an anti-human IL-6 antibody that binds to human IL-6 and to thereby block binding between IL-6 and its receptor are not disclosed.

Since the amino acid sequence of a protein determines its structural and functional properties the changes that can be tolerated in a antibody while retaining similar biological activity or structural specificity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function.

With respect to claim 22 and its limitation (emphasis added) "*...wherein one or several amino acids are deleted, substituted or added in the amino acid sequences of said VH chain and/or said VL chain*, wherein said Vh chain and Vl chain bind to human IL-6 to thereby block binding between Il-6 and its receptor", essentially as stated in the prior Office Action mailed October 17, 2007, this limitation given its broadest reasonable interpretation consistent with the instant specification and the knowledge in the art, comprises amino acid deletions and/or substitutions and/or additions in the Vh and/or Vl chains, without an upper limit on the number of changes given that the claims recite "one or several" and the meaning of "several" is not defined in the instant specification.

Applicant argues that the instant specification puts the skilled artisan in possession of the breadth of this claim because the claim recites the functional limitation "wherein said Vh chain and Vl chain bind to human IL-6 to thereby block binding between Il-6 and its receptor" in conjunction with the structural limitation "wherein one or several amino acids are deleted, substituted or added in the amino acid sequences of said VH chain and/or said VL chain."

Applicant's arguments have been considered, but have not been found convincing, essentially for the reasons of record as put forth in the Office Action mailed October 17, 2007.

The instant specification does not provide sufficient direction or guidance as to which particular amino acid residues of the claimed antibody can be changed and the specific nature of the change, i.e., deletion, insertion or substitution, without ablating the ability of the antibody to bind IL-6, essentially for the reasons stated in Section 4 above with respect to the unpredictability in the art with respect to the structural flexibility and functional importance vis a vis antibody binding of any given CDR and or framework residue within an antibody.

Moreover, with respect to newly added limitation "to thereby block binding between Il-6 and its receptor," the instant specification does not provide sufficient direction or guidance as to the common antibody structure that is required for blocking the interaction of IL-6 with its various receptors and thus the disclosure of the instant specification is insufficient to establish possession of the claimed antibodies, essentially for the reasons stated in Section 4 above with respect to the diverse and distinct interactions between IL-6 and the IL-6Rα polypeptide, or between IL-6 and gp130 in the context of an IL-6/IL-6Rα complex, or between IL-6 to α2-macroglobulin.

Without this guidance or direction the skilled artisan would not consider applicant to be in possession of the claimed genus of gene fragments because the skilled artisan recognizes that even seemingly minor changes made without guidance or direction as to the relationship between the particular amino acid sequence of the instantly claimed gene fragments and its ability to bind antigen, can dramatically affect antigen-antibody binding.

Sufficient description to show possession of such a genus "may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997). Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. *See University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004).

Without a correlation between structure and function, the claim does little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement. *See Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 ("definition by function … does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is").

Moreover, according to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, especially page 1106 3rd column, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed

correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. See, MPEP 2163 II.A.3a.ii.

Applicant is directed to the Revised Guidelines for the Examination of Patent Applications Under the 35 U.S.C.112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No.4, pages 1099-1111, Friday January 5, 2001).

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
April 29, 2008

/Michail A Belyavskyi/
Primary Examiner, Art Unit 1644